OCT 2 1 2005

Section 3

K 052121

GEM Premier 3000: Extension of Glucose and Lactate Reportable Ranges 510(k) Summary (Summary of Safety and Effectiveness)

Submitted by:

Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421

Contact Person:

Carol Marble, Regulatory Affairs Director
Phone: 781-861-4467 / Fax: 781-861-4207

Summary Prepared:

August 4, 2005

Name of the Device:

GEM Premier 3000

Classification Name:

CGA	Glucose Oxidase, Glucose	
862.1345	Glucose Test System	Class II
KHP	Lactic Acid, Lactate	
862.1450	Lactic Acid Test System	Class I

Identification of predicate device:

K022158 GEM Premier 3000

Description of the modified device:

The GEM Premier 3000 is a portable system for use by health care professionals to rapidly analyze whole blood samples at the point of health care delivery in a clinical setting that was originally cleared for the U.S. market under K992834, with glucose and lactate parameters added under K010520 and Intelligent Quality Management (iQM) introduced under K022158.

The reportable ranges for the Glucose and Lactate parameters are being extended through additional performance testing with the release of a new software version.

Statement of Technological Characteristics of the Device Compared to Predicate Device:

The GEM Premier 3000 with extended reportable ranges for Glucose and Lactate is substantially equivalent in performance, intended use, safety and effectiveness to the currently marketed GEM Premier 3000.

Performance Data Summary:

Based on detection limit testing and the linearity data presented below, the claimed reportable ranges in the Operator's Manual were extended for glucose from "20 to 500 mg/dL" to "5 to 500 mg/dL" and lactate from "0.3 to 15 mmol/l" to "0.2* to 15 mmol/l":

Parameter	N per Level	Slope	Intercept	R2
Glucose (mg/dL)	30-32	1.012	-1.369	0.997
Lactate (mmol/L)	32-33	1.031	-0.028	0.999

*NOTE: Due to the instability of Lactate in whole blood, samples used to establish the 0.2 mmol/L concentration were stabilized through repeated washing and icing *in vitro* for testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 2 1 2005

Ms. Carol Marble
Regulatory Affairs Director
Instrumentation Laboratory Co.
113 Hartwell Avenue
Lexington, MA 02421

Re: k052121
Trade/Device Name: GEM Premier 3000
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CGA, KPH
Dated: October 11, 2005
Received: October 12, 2005

Dear Ms. Marble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K052121

Device Name: GEM Premier 3000

Indications for Use:

The GEM Premier 3000 is a portable system for use by health care professionals to rapidly analyze whole blood samples at the point of health care delivery in a clinical setting. The instrument provides quantitative measurements of whole blood pH, pCO_2, pO_2, Na+, K+, Ca++, Glucose, Lactate and Hct. These parameters along with derived parameters aid in the diagnosis of a patient's acid/base status, oxygen delivery capacity, and electrolyte and metabolite balance.

Prescription Use √	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Tracy Phillips

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K052121